continuing overt off-label marketing of Fentora as a result of that settlement agreement (which was made final and signed in September, 2008). Nonetheless, Cephalon continued to reap the benefits of past off-label marketing efforts of both Actiq and Fentora based on the momentum and established prescription patterns caused by such prior off-label marketing efforts. Approximately 80% of Actiq sales remained off label at the time the switching effort began.

82. Additionally, Relator has learned that at the end of 2008 or in early 2009, Cephalon management again began encouraging its sales force to urge use of Fentora for off-label indications. Indeed, Robert Roche, who was until recently was Cephalon's Sr. V.P. of Marketing Marketing and Sales, reportedly informed sales representatives in 2009 that Cephalon was losing too much money by abandoning off-label marketing efforts on its drugs and thus that it would be worth a second fine to return to those past practices.

83. Cephalon now markets Fentora off label to the same kinds of internists, general practitioners, and family practitioners, with the same kinds of risks to patients as exist with respect to off-label marketing of Actiq. In addition to the risks inherent in all opioids that it shares with Actiq, Fentora introduced additional risks associated with the possibility that patients might accidently swallow the tablets whole. Especially for children, that risk increased concerns about potential overdosing.

84. Because of the narrow scope of its FDA marketing approval (breakthrough cancer pain for opioid tolerant patients), and the significantly more lucrative profits promised by the off-off-label market, Cephalon focused its marketing efforts for Fentora primarily on off-label uses just as it had done with Provigil, Gabitril, and Actiq before 2007. Through a strong push by Cephalon and its sales force to convert doctors from prescribing Actiq to prescribing Fentora

instead, Cephalon has sought and continues to seek to reap the economic benefits from the improper sales conduct it used to capture the huge off-label market for sales of Actiq. Currently, Fentora is marketed off label by Cephalon principally through peer-to-peer speaker programs at lunches and dinners. Sales representatives also call on pain specialists approximately 80% of the the time, rather than focusing on oncologists, who would be the primary prescribers for Fentora's on-label indication. It is likely that more than 80% of Fentora sales are associated with off-label uses.

85. Additionally, during at least the earliest days of Cephalon's off-label promotion of Fentora, it sales representatives were inaccurately advising doctors to prescribe dosages of Fentora containing the same amount of fentanyl as patients had been given with Actiq. Because, however, Fentora's method of delivering the drug to the bloodstream is more efficient than Actiq's, such incorrect advice led to increased overdoses by patients on Fentora and to increased incidents of overdose deaths.

B. Cephalon Is Illegally Promoting Nuvigil.

86. Nuvigil, a once-daily successor drug to Provigil (which is taken twice daily), obtained FDA approval in June 2007 to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome, narcolepsy, and shift work sleep disorder. Cephalon, however, did not launch the product in the market place until June, 2009. Since Nuvigil was first launched, Cephalon has aggressively promoted Nuvigil for off-label use in much the same manner that it has marketed Provigil, Gabitril, Actiq, and Fentora.

87. Because Provigil is going off patent soon and is subject to possible patent challenges by generic manufacturers that may seek to further expedite loss of Cephalon's patent protection,

Cephalon is now engaged in a marketing strategy (launched in June, 2009) to convert current Provigil prescribers that it gained through its prior off-label marketing efforts into prescribers of Nuvigil. Cephalon hopes to limit the financial losses it is likely to suffer once generic competition to Provigil enters the market, by exececuting a strategy similar to the one it pursued with regard to Actiq and Fentora. To accomplish this effort, Cephalon currently sells Nuvigil at a a price 10% below what it charges for Provigil and also has offered voucher programs ranging from free 30-day prescriptions to Nuvigil to $50 coupons for the drug. This reduces patients' costs for Nuvigil to as little as $3 for a one-month prescription.

88. Nuvigil (armodafinil) is not a precise chemical or delivery-form equivalent of Provigil (modafinil) and thus has its own, new patent protection. Consequently, it does not face competition from true generic equivalents and can be sold at higher prices demanded for brand name drugs without generic competition.

89. Cephalon's sales force has thus shifted its marketing emphasis for wakefulness-promoting medications from Provigil to Nuvigil, which it now markets off-label to the same kinds of physicians–particularly psychiatrists and child psychiatrists–with the same kinds of risks to patients as existed with respect to the off-label marketing of Provigil. Indeed, nationally, of the top twenty prescribers of Nuvigil during its first three months of promotion (June thru August, 2009), twelve were doctors who practiced in medical specialties who would not normally be expected to treat patients for any of Nuvigil's on-label indications. Each such doctor was visited repeatedly by his or her Cephalon sales representative during that period of time (total contacts during the period ranged from 9 to 31 for each physician). These national-top-20 prescribers with off-label practice specialties included: anesthesiologists (Dr. Kiulu Ruan of

Mobile, Alabama), psychiatrists (Drs. Charles Devine of Brandon, Florida; Charles Price of Reno, Nevada; Ronald Kurlander of Pomoano Beach, Florida, Roya Ghadimi of Danbury, Connecticut; and Ulla Laakso of New York, New York), pain management specialists (Drs. Bart Gatz of Boynton Beach, Florida; Steven Simon of Leawood, Kansas; John Winfield of Boone, North Carolina; and Kathleen Rathbun of Lake Worth, Florida),and OB/GYNs (Drs. John Lee of Milton, Florida and Chevies Newman of Hammond, Louisiana). Rheumatologists are another off-label physician target group, for their patients with fibromyalgia and chronic fatigue.

90. In light of the narrow scope of its FDA marketing approval, and the considerably more lucrative profits promised by the off-label uses for Nuvigil, Cephalon has focused its marketing efforts for Nuvigil primarily on off-label uses,. As noted above, on-label indications for Nuvigil are limited to adult patients with obstructive sleep apnea, narcolepsy, and shift work sleep disorder. Cephalon sales representatives, however, routinely market Nuvigil for daytime drowsiness associated with jet lag, depression, anxiety, bipolar disorder, adult and child ADHD, schizophrenia, treatment for sleepiness side effects of other medications (including opioids), weight loss, hindering the need for sleep, and improvement of athletic performance or improvement of brain function associated with test taking. Cephalon sales representatives market Nuvigil to child psychiatrists for treatment of psychiatric maladies included among the above disorders, despite the fact that the drug has not been studied in pediatric patients and has expressly not been approved for use in pediatric patients for any indication, according to the drug's FDA-approved labeling.

91. Cephalon uses bogus "Medical Education Programs" to market Nuvigil for off-label uses. The speakers at these programs change the content of their presentations depending on who

who is in the audience. If the speakers are aware of any attendees who have a duty to report off-off-label marketing to federal authorities, they will limit their presentations to on-label indications while those people remain present. However, when there are no such attendees present at the event, off-label uses of Nuvigil figure prominently in the presentations.

92. Through a strong push by Cephalon and its sales force to convert former Provigil prescribers to prescribing Nuvigil instead, Cephalon seeks to reap continued economic benefits from the improper sales conduct it used to capture a huge off-label market for sales of Provigil. Approximately 50% of Nuvigil sales currently relate to such off-label uses.

C. Cephalon Is Illegally Promoting Excessive Sales of Amrix.

93. Since it obtained FDA approval in February 2007 to market Amrix for treatment of muscle spasms associated with acute, painful, musculoskeletal conditions, as an adjunct to rest and physical therapy, Cephalon has aggressively promoted Amrix, a skeletal muscle relaxant, for off-label use in much the same manner as it has marketed Provigil, Gabitril, Actiq, Fentora, and Nuvigil.

94. Cephalon's marketing efforts for Amrix are focused primarily on urging off-label treatment protocols designed to increase sales of the drug by encouraging over prescribing.

95. The FDA-approved labeling for Amrix specifies that the drug "should be used only for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use is not available and because muscle spasm associated with acute, painful musculo-skeletal conditions is generally of short duration and specific therapy for longer periods is seldom warranted."

96. Despite the limitations of the FDA's approval on the period of usage, Cephalon's

sales representatives nevertheless market the drug to prescribing physicians for use as a long-long-term muscle relaxant and routinely urge physicians to write prescriptions for the drug for 28-day treatment regimens or longer. As a consequence of such off-label marketing efforts, the average prescription duration for Amrix is 28 days, which is one-third longer than the absolute maximum period of treatment approved by FDA.

97. As a result of such marketing efforts, claims are routinely submitted for reimbursement for Amrix that exceed the amount of medication reasonably warranted for an appropriate period of treatment for *acute* musculoskeletal conditions, as encompassed within the approved indication for the drug. This results in program payments for drugs that are not reasonably expected to be needed or used, because conditions properly treated with Amrix seldom require therapy (much less adjunct medication) for even as much as three weeks.

D. Through its Marketing Partner, Takeda, Cephalon Continued to Market Provigil Off-Label Through 2008.

98. Beginning in July, 2006, Cephalon embarked on a co-promotion agreement and conspiracy with Takeda, to market Provigil in the United States. Under the agreement, Cephalon retained all responsibility for the development, manufacture, distribution and sale of Provigil and paid Takeda royalties based on sales criteria set forth in the agreement. Cephalon and Takeda also formed a joint commercial committee to manage the promotion of that drug. This arrangement between the two companies remained in effect until Takeda withdrew from the arrangement effective November 1, 2008.

99. During the entire term of the agreement and conspiracy, Takeda participated in the same off-label marketing schemes with respect to Provigil in which Cephalon had engaged until

September, 2007. However, while Cephalon thereafter temporarily ceased its off-labeling marketing practices because of the settlement in principle with the United States and the States and the District of Columbia based on Relator's and other whistleblowers' original False Claims Act lawsuits, Cephalon made no effort to cause Takeda to change the off-labeling marketing practices it had previously agreed with Cephalon to undertake, and Takeda in fact continued to engage in such practices unabated. Cephalon knowingly permitted Takeda to continue to engage in such practices, and Cephalon knowingly continued to reap the benefits of such off-label marketing by Takeda through October, 2008.

Count I
Federal False Claims Act
31 U.S.C. §§3729(a)(1), (2) and (3) (1986)
31 U.S.C. §§3729(a)(1)(A), (B) and (C) (2009)

100. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 99 of this Complaint.

101. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended, relating to Cephalon's marketing of Fentora, Nuvigil, Amrix, and Provigil, and Takeda's marketing of Provigil.

102. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

103. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Government to approve and pay such false and fraudulent claims.

104. Because of the conspiracy that defendants entered in to with respect to the marketing of Provigil, Cephalon is equally liable with Takeda for Takeda's conduct as alleged herein.

105. Each prescription that was written as a result of defendant's illegal off-label marketing practices represents a false or fraudulent record or statement. Each reimbursement claim for such off-label and illegally induced prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

106. Relator cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false claims were presented by thousands of separate entities entities across the United States since 2006. Relator has no control over or dealings with such entities, and has no access to the records in their possession.

107. The Government, unaware of the falsity of the records. statements and claims made or caused to be made by the defendants, paid and continues to pay claims that would not be paid but for defendants' illegal off-label marketing practices and illegal inducements.

108. By reason of the defendants' acts, the United States has been damaged, and continues to be damaged, in an amount to be determined at trial. Federal health insurance programs likely also have paid claims for off-label prescriptions for indications that were not approved by the FDA and/or for prescriptions that were illegally induced by Cephalon and Takeda through their off-labeling marketing efforts.

Count II
California False Claims Act
Cal Gov Code §12651(a)(1), (2) and (3)

109. Relator realleges and incorporates by reference the allegations contained in para-

graphs 1 through 108 of this Complaint.

110. This is a claim for treble damages and penalties under the California False Claims Act, relating to Cephalon's marketing of Fentora, Nuvigil, Amrix, and Provigil and to Takeda's marketing of Provigil.

111. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

112. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

113. Because of the conspiracy that defendants entered in to with respect to the marketing of Provigil, Cephalon is jointly and severally liable with Takeda for Takeda's conduct as alleged herein.

114. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for Cephalon's and Takeda's illegal off-label marketing practices and inducements.

115. By reason of the defendants' acts, the State of California has been damaged, and continues to be damaged, in an amount to be determined at trial.

Count III
Connecticut False Claims Act
Conn. Pub. Law 09-05 §2(a)(1), (2) and (3)

116. Relator realleges and incorporates by reference the allegations contained in

paragraphs 1 through 108 of this Complaint.

117. This is a claim for treble damages and penalties under the Connecticut False Claims Act, relating to Cephalon's marketing of Fentora, Nuvigil, Amrix, and Provigil and to Takeda's marketing of Provigil.

118. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Connecticut State Government for payment or approval.

119. By virtue of the acts described above, defendants knowing made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Connecticut State Government to approve and pay such false and fraudulent claims.

120. Because of the conspiracy that defendants entered in to with respect to the marketing of Provigil, Cephalon is jointly and severally liable with Takeda for Takeda's conduct as alleged herein.

121. The Connecticut State Government, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for Cephalon's and Takeda's illegal off-label marketing practices and illegal inducements.

122. By reason of defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

Count IV
Delaware False Claims And Reporting Act
6 Del C. §1201(a)(1), (2) and (3)

123. Relator realleges and incorporates by reference the allegations contained in para-